

## § 1304.21

lysergic acid diethylamide), or less than 0.5 gram of lysergic acid diethylamide, is on hand at the time of inventory, that substance need not be included in the inventory. Laboratories of the Administration may possess up to 150 grams of any hallucinogenic substance in Schedule I without regard to a need for an inventory of those substances. No inventory is required of known or suspected controlled substances received as evidentiary materials for analysis.

(6) *Inventories of dispensers and researchers.* Each person registered or authorized to dispense or conduct research with controlled substances shall include in the inventory the same information required of manufacturers pursuant to paragraphs (e)(1)(iii) and (iv) of this section. In determining the number of units of each finished form of a controlled substance in a commercial container that has been opened, the dispenser or researcher shall do as follows:

(i) If the substance is listed in Schedules I or II, make an exact count or measure of the contents; or

(ii) If the substance is listed in Schedule III, IV, or V, make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case he/she must make an exact count of the contents.

(7) *Inventories of collectors.* Each registrant authorized to collect controlled substances from ultimate users shall include in the inventory the following information:

(i) For registrants authorized to collect through a mail-back program, the record shall include the following information about each unused mail-back package and each returned mail-back package on hand awaiting destruction:

(A) The date of the inventory;

(B) The number of mail-back packages; and

(C) The unique identification number of each package on hand, whether unused or awaiting destruction.

(ii) For registrants authorized to collect through a collection receptacle, the record shall include the following information about each unused inner

## 21 CFR Ch. II (4–1–21 Edition)

liner on hand and each sealed inner liner on hand awaiting destruction:

(A) The date of the inventory;

(B) The number and size of inner liners (e.g., five 10-gallon liners, etc.);

(C) The unique identification number of each inner liner.

[62 FR 13959, Mar. 24, 1997, as amended at 68 FR 41228, July 11, 2003; 79 FR 53562, Sept. 9, 2014]

### CONTINUING RECORDS

#### § 1304.21 General requirements for continuing records.

(a) Every registrant required to keep records pursuant to § 1304.03 shall maintain, on a current basis, a complete and accurate record of each substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of by him/her, and each inner liner, sealed inner liner, and unused and returned mail-back package, except that no registrant shall be required to maintain a perpetual inventory.

(b) Separate records shall be maintained by a registrant for each registered location except as provided in § 1304.04 (a). In the event controlled substances are in the possession or under the control of a registrant at a location for which he is not registered, the substances shall be included in the records of the registered location to which they are subject to control or to which the person possessing the substance is responsible.

(c) Separate records shall be maintained by a registrant for each independent activity and collection activity for which he/she is registered or authorized, except as provided in § 1304.22(d).

(d) In recording dates of receipt, distribution, other transfers, or destruction, the date on which the controlled substances are actually received, distributed, otherwise transferred, or destroyed will be used as the date of receipt, distribution, transfer, or destruction (e.g., invoices or packing slips, or DEA Form 41). In maintaining records concerning imports and exports, the registrant must record the anticipated date of release by a customs official for permit applications and declarations and the date on which the controlled substances are released by a customs

officer at the port of entry or port of export for return information.

(e) *Record of destruction.* In addition to any other recordkeeping requirements, any registered person that destroys a controlled substance pursuant to § 1317.95(d), or causes the destruction of a controlled substance pursuant to § 1317.95(c), shall maintain a record of destruction on a DEA Form 41. The records shall be complete and accurate, and include the name and signature of the two employees who witnessed the destruction. Except, destruction of a controlled substance dispensed by a practitioner for immediate administration at the practitioner's registered location, when the substance is not fully exhausted (e.g., some of the substance remains in a vial, tube, or syringe after administration but cannot or may not be further utilized), shall be properly recorded in accordance with § 1304.22(c), and such record need not be maintained on a DEA Form 41.

[36 FR 7792, Apr. 24, 1971, as amended at 36 FR 13386, July 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, as amended at 62 FR 13960, Mar. 24, 1997; 79 FR 53563, Sept. 9, 2014; 81 FR 97020, Dec. 30, 2016]

**§ 1304.22 Records for manufacturers, distributors, dispensers, researchers, importers, exporters, registrants that reverse distribute, and collectors.**

Each person registered or authorized (by §§ 1301.13(e), 1307.11, 1307.13, or part 1317 of this chapter) to manufacture, distribute, dispense, import, export, reverse distribute, destroy, conduct research with controlled substances, or collect controlled substances from ultimate users, shall maintain records with the information listed in paragraphs (a) through (f) of this section.

(a) *Records for manufacturers.* Each person registered or authorized to manufacture controlled substances shall maintain records with the following information:

(1) For each controlled substance in bulk form to be used in, or capable of use in, or being used in, the manufacture of the same or other controlled or noncontrolled substances in finished form,

- (i) The name of the substance;
- (ii) The quantity manufactured in bulk form by the registrant, including

the date, quantity and batch or other identifying number of each batch manufactured;

(iii) The quantity received from other persons, including the date and quantity of each receipt and the name, address, and registration number of the other person from whom the substance was received;

(iv) The quantity imported directly by the registrant (under a registration as an importer) for use in manufacture by him/her, including the date, quantity, and import permit or declaration number for each importation;

(v) The quantity used to manufacture the same substance in finished form, including:

(A) The date and batch or other identifying number of each manufacture;

(B) The quantity used in the manufacture;

(C) The finished form (e.g., 10-milligram tablets or 10-milligram concentration per fluid ounce or milliliter);

(D) The number of units of finished form manufactured;

(E) The quantity used in quality control;

(F) The quantity lost during manufacturing and the causes therefore, if known;

(G) The total quantity of the substance contained in the finished form;

(H) The theoretical and actual yields; and

(I) Such other information as is necessary to account for all controlled substances used in the manufacturing process;

(vi) The quantity used to manufacture other controlled and noncontrolled substances, including the name of each substance manufactured and the information required in paragraph (a)(1)(v) of this section;

(vii) The quantity distributed in bulk form to other persons, including the date and quantity of each distribution and the name, address, and registration number of each person to whom a distribution was made;

(viii) The quantity exported directly by the registrant (under a registration as an exporter), including the date, quantity, and export permit or declaration number of each exportation;